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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,741	04/03/2001	Arthur W. Zikorus	VNUS-57380	4515

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EXAMINER

ROY, BAISAKHI

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/825,741	Applicant(s) ZIKORUS ET AL.	
	Examiner Baisakhi Roy	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 35-41, 50-53 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 35-41, 50-53, and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-15 and 19-22 have been fully considered but they are not persuasive. The claim is directed to the application of energy to the treatment site and eventually leading to a smaller tissue size by cutting tissue, it is still applying energy to the structure and eventually leading to a smaller structure (col. 19 lines 8-28).
2. Applicant's arguments with respect to claims 50-53 and 70-72 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn et al. (5830224).

Cohn et al. disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2).

Cohn et al. teach emitting light from a fiber optic device by introducing the catheter over a fiber optic device and removing the fiber optic device after the step of

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measuring the length of the device into the patient until the attribute of light changes (col. 25 lines 16-33, col. 27 lines 25-61).

The reference teaches generating a magnetic field at the working end of the catheter and sensed by the catheter (col. 21 lines 64-67, col. 22 lines 1-63).

The reference teaches introducing the catheter over a guide wire and generating a magnetic field at and by the guide wire (col. 23 lines 25-30 lines 47-67, col. 24 lines 1-18).

The reference teaches generating a radio-frequency signal at the catheter and sensed by the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15).

The reference teaches generating an ultrasound signal at the working end of the catheter and sensed by the catheter and introducing the catheter over the guide wire with an ultrasound signal generated by the guide wire and sensed by the guide wire (col. 26 lines 4-65, col. 28 lines 1-11, col. 30 lines 28-36, col. 31 lines 9-28).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Leschinsky et al. (5728122). Cohn et al. do not explicitly

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teach the guide wire to have a hook shaped tip at the distal end. In the same field of endeavor, Leschinsky et al. disclose a guide wire with a hook shaped tip located at the working end of the catheter (col. 13 lines 43-47). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Leschinsky et al. to modify the teaching by Cohn et al. for the purpose of enabling a more efficient anchoring mechanism to attach to the structure of interest.

5. Claims 35, 37, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Leschinsky et al. Flaherty et al. disclose a method of positioning a catheter within a hollow anatomical structure by determining a desired location within the hollow structure, marking the location, introducing a catheter having a working end with a transducer into the hollow structure, identifying the location of the transducer, and positioning the working end of the catheter at the desired location within the structure (col. 3 lines 23-67, col. 6 lines 6-16 lines 60-67, col. 11 lines 6-22, col. 19 lines 9-43, col. 23 lines 1-33, and claims 1, 5). The reference teaches using a device to be controlled by the operator positioned over the hollow structure, which identifies the location of the transducer (col. 3 lines 23-60), generating a magnetic field at the working end of the catheter (col. 4 lines 20-47), and an ultrasound signal at the working end of the catheter (col. 2 lines 41-55). Flaherty et al. however do not explicitly teach the use of external markers. Leschinsky et al. however do teach the use of reference marks (col. 2 lines 25-29). It would have therefore been obvious to one of ordinary skill in the art to use the Leschinsky et al. teaching to modify the teaching by

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Flaherty et al. for the purpose of allowing more precise determination of the location of the vessel puncture (col. 2 lines 24-25).

6. Claim 36, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Leschinsky et al. and further in view of Cohn et al.

Flaherty et al. and Leschinsky et al. do not explicitly address the sapheno-femoral junction. Cohn et al. as discussed previously disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Cohn et al. to modify the teaching by Flaherty et al. and Leschinsky et al. for the purpose of enabling a more detailed study of the sapheno-femoral junction and reduce the structure to a smaller size.

Flaherty et al. do not teach generating a radio-frequency field at the working end of the catheter. Cohn et al. teach a method of positioning a catheter within a hollow anatomical structure with the generation of a radio-frequency field at the working end of the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15). It would have therefore been obvious to one of ordinary skill in the art to use the radio-frequency teaching by Cohn et al. to modify the teaching by Flaherty et al. for the purpose of obtaining feedback from the catheter from a radio-frequency signal.

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7. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. in view of Cohn et al. Leschinsky et al. do not explicitly teach using the apparatus near the vicinity of the sapheno femoral junction. Cohn et al. as discussed previously disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Cohn et al. to modify the teaching by Leschinsky et al. for the purpose of providing a more detailed examination of a specific site of interest.

8. Claims 50, 52, 53, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. (5728122) in view of Tu (6235024). Leschinsky disclose a method of positioning a catheter within a hollow anatomical structure by introducing a guide wire having a hook-shaped tip, hooking the hook-shaped tip of the guide wire to the structure of interest, introducing a catheter having a working end into the hollow structure over the guide wire, and positioning the working end of the catheter proximate the structure of interest (abstract, col. 2 lines 8-23 lines 62-67 lines 1-5, col. 13 lines 43-46), and measuring the length of the guide wire (col. 9 lines 26-42). Leschinsky does not teach the use of an energy application device at the treatment site. In the same field of endeavor Tu discloses an ablation catheter system with an ablation element having dual capability of radiofrequency ablation and ultrasound ablation to treat tissue and reduce the size of the tissues without cutting the anatomical structure

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(abstract, col. 2 lines 5-10). It would have therefore been obvious to one of ordinary skill in the art to use the teaching Tu to modify the teaching by Leschinsky et al. for the purpose of treating tissues and improved constructions for an ablation catheter system (col. 1 lines 1-10).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

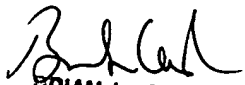
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

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